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| 09/942,241 | 08/29/2001 | Krishan Chari | 82300D-W | 9136 |

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|---|---|
| 1634 | |

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/942,241 | CHARI ET AL. | |
| | Examiner | Art Unit | |
| | BJ Forman | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-24,26-34 and 43-51* is/are pending in the application.

4a) Of the above claim(s) *44-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24,26-34,43,50 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4 December 2003 has been entered.

***Status of the Claims***

2. This action is in response to papers filed 4 December 2003 in which claims1, 2, 6, 18-20, 24, 27, 29 were amended and claims 44-51 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 4 August 2003 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed and are discussed below as they apply to the amended claims. New grounds for rejection are discussed.

***Election/Restrictions***

3. Newly submitted claims 44-49 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The original and newly claimed inventions are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. Specifically, the microarray of Invention I can be made by random spotting the composition onto a substrate thereby providing a substrate spot-coated with the composition.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 44-49 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise

proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Claims 1-24, 26-34, 43, 50 and 51 are under prosecution.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-8, 13, 15-17, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Sutton et al (U.S. Patent No. 5,714,340, issued 3 February 1998).

Regarding Claim 1, Sutton et al disclose a coating composition comprising microspheres (beads) dispersed in a fluid containing a coating aid and a gelling agent wherein the gelling agent forms a gel (Column 3, lines 3-10; Column 6, line 55-Column 7, line 27; and Column 11, lines 53-57) wherein the gel is capable of immobilizing the microspheres at random positions on a substrate (Fig. 2-5 illustrate the "receptor beads" randomly positioned on the substrate, Column 9, line 32-Column 10, line 15).

Regarding Claim 2, Sutton et al disclose the support is not premarked and does not contain microwells (Column 9, lines 33-41 and Fig. 1-7).

Regarding Claim 3, Sutton et al disclose the composition wherein the pattern is maintained upon gelling (Column 7, lines 33-41 and Fig. 2-5).

Regarding Claim 4, Sutton et al disclose the composition wherein the microspheres are chemically functionalized to have surface active sites (Column 2, lines 32-34 and Column 5, line 27-Column 6, lines 28).

Regarding Claim 5, Sutton et al disclose the composition wherein the active sites carry organic or inorganic attachments (Column 2, lines 32-34 and Column 5, line 27-Column 6, lines 28).

Regarding Claim 6, Sutton et al disclose the composition wherein the active site has organic or inorganic attachments thereon that are capable of chemical or physical interaction (Column 2, lines 32-34 and Column 5, line 27-Column 6, lines 28).

Regarding Claim 7, Sutton et al disclose the composition wherein the active site is bioactive (Column 2, lines 32-34 and Column 5, line 27-Column 6, lines 28).

Regarding Claim 8, Sutton et al disclose the composition wherein the bioactive site interacts with proteins or fragments thereof (Column 10, lines 15-39).

Regarding Claim 13, Sutton et al disclose the composition wherein the gelling agent undergoes thermal gelation (e.g. 37° C, Column 19, lines 10-28).

Regarding Claim 15, Sutton et al disclose the composition wherein the microspheres have a mean diameter of between 1 and 50 microns (Column 5, lines 11-32). It is noted that both the "bead spreading layer" and the "receptor layer" of Sutton et al meet the limitations of Claim 1.

Regarding Claim 16, Sutton et al disclose the composition wherein the microspheres have a mean diameter of between 3 and 30 microns (Column 5, lines 11-32).

Regarding Claim 17, Sutton et al disclose the composition wherein the microspheres have a mean diameter of between 5 and 20 microns (Column 5, lines 11-32).

Regarding Claim 21, Sutton et al disclose the composition wherein the microspheres comprise a synthetic or natural polymeric material (Column 5, lines 11-32).

7. Claims 1-24, 26-34, 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Pierce et al (U.S. Patent No. 4,258,001, issued 24 March 1981).

Regarding Claim 1, Pierce et al disclose a coating composition comprising microspheres (beads) dispersed in a fluid containing a coating aid and a gelling agent wherein the gelling agent forms a gel (Abstract and Column 16, line 55-Column 18, line 39) wherein the gel is capable of immobilizing the microspheres at random positions on a substrate (Fig. 2-14 illustrate randomly positioned beads on the substrate (Column 17 lines 1-67).

Regarding Claim 2, Pierce et al disclose the support is not premarked and does not contain microwells (Column 24, line 65-Column 25, line 5 and Fig. 2-14).

Regarding Claim 3, Pierce et al disclose the composition wherein the pattern is maintained upon gelling (Column 19, lines 48-65).

Regarding Claim 4, Pierce et al disclose the composition wherein the microspheres are chemically functionalized to have surface active sites (Column 30, line 32-Column31, line 44).

Regarding Claim 5, Pierce et al disclose the composition wherein the active sites carry organic or inorganic attachments (Column 30, line 32-Column31, line 44).

Regarding Claim 6, Pierce et al disclose the composition wherein the active site has organic or inorganic attachments thereon that are capable of chemical or physical interaction (Column 30, line 32-Column31, line 44).

Regarding Claim 7, Pierce et al disclose the composition wherein the active site is bioactive (Column 30, line 32-Column31, line 44).

Regarding Claim 8, Pierce et al disclose the composition wherein the bioactive site interacts with proteins or fragments thereof (Column 30, line 32-Column31, line 44).

Regarding Claim 9, Pierce et al disclose the composition wherein the microsphere contains a signature (Column 31, lines 9-19).

Regarding Claim 10, Pierce et al disclose the composition wherein the signature comprises an oil-soluble dye (Column 31, lines 9-19).

Regarding Claim 11, Pierce et al disclose the composition wherein the signature is interrogatable by optical means (Column 31, lines 9-19).

Regarding Claim 12, Pierce et al disclose the composition wherein the gelling agent is gelatin i.e. the microspheres within the composition are coated with gelatin therefore the composition comprises a gelatin gelling agent (Column 30, lines 49-54).

Regarding Claim 13, Pierce et al disclose the composition wherein the gelling agent undergoes thermal gelation (Column 19, lines 48-65).

Regarding Claim 14, Pierce et al disclose the composition wherein the gelling agent is gelatin i.e. the microspheres within the composition are coated with gelatin therefore the composition comprises a gelatin gelling agent (Column 30, lines 49-54).

Regarding Claim 15, Pierce et al disclose the composition wherein the microspheres have a mean diameter of between 1 and 50 microns (Column 9, lines 35-64).

Regarding Claim 16, Pierce et al disclose the composition wherein the microspheres have a mean diameter of between 3 and 30 microns (Column 9, lines 35-64).

Regarding Claim 17, Pierce et al disclose the composition wherein the microspheres have a mean diameter of between 5 and 20 microns (Column 9, lines 35-64).

Regarding Claims 18-20, Pierce et al disclose the composition wherein the microsphere range in size from 1 to 200 microns (Column 9, lines 40-41). The instant claims are drawn to microspheres "capable of being" immobilized at concentrations 100-1 million/$cm^2$; 1,000 to 200,00 / $cm^2$; and 10,000 to 100,00/$cm^2$. While Pierce do not teach a density of immobilization, the 1 micron microspheres of Pierce are clearly capable of being immobilized at the claimed densities as claimed. Therefore, Pierce discloses the claimed microspheres.

Regarding Claim 21, Pierce et al disclose the composition wherein the microspheres comprise a synthetic or natural polymeric material (Table I, Column 13, lines 8-44).

Regarding Claim 22, Pierce et al disclose the composition wherein the polymeric material is amorphous i.e. polystyrene(Table I, Column 13, lines 8-44).

Regarding Claim 23, Pierce et al disclose the composition wherein the polymeric material is amorphous i.e. polystyrene (Table I, Column 13, lines 8-44).

Regarding Claim 24, Pierce et al disclose the composition wherein at least one active site comprises a functionality as claimed (Column 10, line 56-Column 13, line 4).

Regarding Claim 26, Pierce et al disclose the composition wherein the microspheres are prepared by emulsion polymerization (Column 10, lines 42-65).

Regarding Claim 27, Pierce et al disclose a microarray comprising a substrate coated with a composition comprising microspheres (beads) dispersed in a fluid containing a coating aid and a gelling agent wherein the gelling agent forms a gel (Column 8, lines 24-27 and Column 16, line 55-Column 18, line 39) wherein the gel is capable of immobilizing the

microspheres at random positions on a substrate (Fig. 2-14 illustrate randomly positioned beads on the substrate (Column 17 lines 1-67).

Regarding Claim 28, Pierce et al disclose the microarray wherein the substrate is free of receptors designed to physically or chemically interact with the microspheres (Column 24, line 65-Column 25, line 37) whereby the microspheres remain stably dispersed within the carrier i.e. not interacting with the support (Column 17, lines 1-21 and Column 18, lines 1-24).

Regarding Claim 29, Pierce et al disclose the microarray the positions of the microspheres is preserved upon gelling i.e. stable dispersion (Column 17, lines 1-21 and Column 19, lines 48-65).

Regarding Claim 30, Pierce et al disclose the microarray wherein the gelling agent is gelatin i.e. the microspheres within the composition are coated with gelatin therefore the composition comprises a gelatin gelling agent (Column 30, lines 49-54).

Regarding Claim 31, Pierce et al disclose the microarray wherein the microspheres bear chemically active sites (Column 10, line 56-Column 13, line 3 and Column 30, line 32-Column31, line 44).

Regarding Claim 32, Pierce et al disclose the microarray wherein the active site is bioactive (Column 30, line 32-Column31, line 44).

Regarding Claim 33, Pierce et al disclose the microarray wherein the substrate comprises glass, plastic, cellulose acetate (Column 24, line 65-Column 25, line 37).

Regarding Claim 34, Pierce et al disclose the microarray wherein the substrate is flexible e.g. paper (Column 25, lines 1-3).

Regarding Claim 43, Pierce et al disclose the microarray wherein the support is not premarked and does not contain microwells (Column 24, line 65-Column 25, line 5 and Fig. 2-14).

8. Claims 50 and 51 are rejected under 35 U.S.C. 102 (e) as being anticipated by Charych et al (U.S. Patent No. 6,306,598, filed 21 June 1999).

Regarding Claim 50, Charych et al disclose a coating composition comprising microspheres (colloids) dispersed in a fluid, the fluid comprising a precursor to a gelling agent capable of sol-to-gel transition to a gel thereby immobilizing the microspheres (Column 43, line 58-Column 45, line 6 and Examples 8, 9 and 11).

Regarding Claim 51, Charych et al disclose a microarray comprising a substrate coated with randomly immobilized microspheres in a gel (Column 43, line 58-Column 45, line 6 and Examples 8, 9 and 11).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-11, 15-24, 27-29 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (WO 00/16101, published 23 March 2000) in view of McGall et al (U.S. Patent No. 6,147,205, filed 5 March 1997).

Regarding Claim 1, Walt et al disclose a coating composition comprising a gelling agent and microspheres dispersed in a fluid (i.e. solution, page 22, lines 9-22) wherein upon coating the composition on a substrate, said microspheres become immobilized in the plane of coating and form a random pattern on the substrate i.e. the microspheres are within a solution which upon evaporation (gelling) holds the microspheres in place (page 22, lines 15-16) wherein the gelling agent is selected from polyethylene glycol and polyacrylamide (page 22, lines 20-22) which are defined by the specification as gelling agents.

The specification (page 5, lines 1-15) defines "gelling agent" as a substance that can undergo gelation. Examples include materials such as gelatin, water-soluble cellulose ethers or poly(n-isopropylaclylalnide) that undergo thermal gelation or substances such as poly (vinyl alcohol) that may be chemically 5 cross-linked by a borate compound. Other gelling agents may be polymers that may be cross-linked by radiation such as ultraviolet radiation. Examples of gelling agents include acacia, alginic acid, bentonite, carbomer, carboxymethylcellulose sodium, cetostemyl alcohol, colloidal silicon dioxide, ethylcellulose, gelatin, guar gum, hythoxyetlhylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, magnesium aluminum silicate, maltodextrin, methylcellulose, polyvinyl alcohol, povidone, propylene glycol alginate, sodium alginate, sodium starch glycolate, starch, tragacanth and xanthum gum.

Walt et al do not teach the composition comprises a coating aid. However, coating aids were well known in the art at the time the claimed invention was made as taught by McGall et al. Mc Gall et al specifically teach a coating composition for making a microarray wherein the composition comprises a gelling agent e.g. polyethylene glycol and a coating aid e.g. Triton X-100 (Column 14, lines 4-35). Furthermore McGall et al teach that adding the coating aid to the composition promotes spreading and adhesion of the gelling agent, limits evaporation and promotes longevity of the coated surface (Column 14, lines 29-35). Therefore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the coating composition of Walt et al by adding the coating aid as taught by McGall et al for the expected benefit of promoting spreading and adhesion of the

gelling agent, limiting evaporation and promoting longevity of the coated surface as taught by Walt et al (Column 14, lines 29-35).

Regarding Claim 2, Walt et al teach the coating composition is used for coating a substrate (page 22, lines 9-22) wherein the substrate is planar (page 7, line 14). The instantly claimed "useful for coating" is a recitation of intended use for the composition.

The courts have stated that a claim containing a recitation with respect to the manner in which a claimed product is intended to be employed does not differentiate the claimed product from a prior art product if the prior art product teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Walt et al and McGall et al teach the structural limitations of the claimed composition and therefore, teach the claimed composition.

Regarding Claim 3,Walt et al disclose the composition wherein the random pattern is preserved (i.e. held in place) upon gelling of the gelling agent (page 22, lines 15-16).

Regarding Claim 4, Walt et al disclose the composition wherein the microspheres are chemically functionalized to have surface active sites (page 14, line 28-page 15, line 33).

Regarding Claim 5, Walt et al disclose the composition wherein the surface active sites can carry organic or inorganic attachments (page 10, lines 2-29).

Regarding Claim 6, Walt et al disclose the composition wherein organic or inorganic attachments on the surface of the active site is capable of chemical or physical interaction (page 14, line 28-page 15, line 33).

Regarding Claim 7, Walt et al disclose the composition wherein the surface active site is bioactive (page 10, lines 2-29).

Regarding Claim 8, Walt et al disclose the composition wherein the bioactive site interacts with nucleic acid, protein or fragment thereof (page 10, lines 2-10).

Regarding Claim 9, Walt et al disclose the composition wherein the microsphere contains a signature (page 16, lines 15-33).

Regarding Claim 10, Walt et al disclose the composition wherein the signature is comprised of an oil-soluble dye i.e. the dye is dissolved in an organic solvent (page 17, lines 21-31).

Regarding Claim 11, Walt et al disclose the composition wherein the signature is interrogatable by optical means (page 16, lines 15-33).

Regarding Claim 15, Walt et al disclose the composition wherein the microspheres have a mean diameter of between 1 and 50 microns (page 9, lines 21-23).

Regarding Claim 16, Walt et al disclose the composition wherein the microspheres have a mean diameter of between 3 and 30 microns (page 9, lines 21-23).

Regarding Claim 17, Walt et al disclose the composition wherein the microspheres have a mean diameter of between 5 and 20 microns (page 9, lines 21-23).

Regarding Claim 18, Walt et al disclose the composition wherein the microspheres are immobilized at a concentration of between 100 and 1 million microspheres per $cm^2$ (page 6, lines 21-24).

Regarding Claim 19, Walt et al disclose the composition wherein the microspheres are immobilized at a concentration of between 1,000 and 200,000 microspheres per $cm^2$ (page 6, lines 26-28).

Regarding Claim 20, Walt et al disclose the composition wherein the microspheres are immobilized at a concentration of between 10,000 and 100,00 microspheres per $cm^2$ (page 6, lines 21-28).

Regarding Claim 21, Walt et al disclose the composition wherein the microspheres comprise a synthetic or natural polymeric material (page 9, lines 11-18).

Regarding Claims 22-23, Walt et al disclose the composition wherein the polymeric material is an amorphous polymer i.e. polystyrene (page 9, lines 11-18).

Regarding Claim 24, Walt et al disclose the composition wherein the microsphere contains a surface active site comprising a functionality selected from the group consisting of carboxy, amine, epoxy, hydrazine, aldehyde and combinations thereof (page 10, lines 11-20).

Regarding Claim 27, Walt et al disclose a microarray comprising a substrate coated with a composition comprising microspheres dispersed in a fluid (i.e. solution) wherein the microspheres are immobilized at random positions on the substrate (page 22, lines 9-22) i.e. the microspheres are within a solution which upon evaporation (gelling) holds the microspheres in place (page 22, lines 15-16) wherein the gelling agent is selected from polyethylene glycol and polyacrylamide (page 22, lines 20-22) which are defined by the specification as gelling agents (page 5, lines 1-15).

Walt et al do not teach the composition comprises a coating aid. However, coating aids were well known in the art a the time the claimed invention was made as taught by McGall et al. Mc Gall et al specifically teach a coating composition for making a microarray wherein the composition comprises a gelling agent e.g. polyethylene glycol and a coating aid e.g. Triton X-100 (Column 14, lines 4-35). Furthermore McGall et al teach that adding the coating aid to the composition promotes spreading and adhesion of the gelling agent, limits evaporation and promotes longevity of the coated surface (Column 14, lines 29-35). Therefore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the coating composition of Walt et al by adding the coating aid as taught by McGall et al for the expected benefit of promoting spreading and adhesion of the gelling agent, limiting evaporation and promoting longevity of the coated surface as taught by Walt et al (Column 14, lines 29-35).

Regarding Claim 28, Walt et al disclose the microarray wherein the substrate is free of receptors designed to physically interaction with the microspheres i.e. the substrate is planer and therefore free of receptors (wells) for physical interaction with the microspheres (page 7, line 14).

Regarding Claim 29, Walt et al disclose the microarray wherein the random pattern is preserved (i.e. held in place) upon gelling of the gelling agent (page 22, lines 15-16).

Regarding Claim 31, Walt et al disclose the microarray wherein the microspheres bear chemically active sites (page 10, lines 2-29).

Regarding Claim 32, Walt et al disclose the microarray wherein the chemically active site is bioactive (page 10, lines 2-29).

Regarding Claim 33, Walt et al disclose the microarray wherein the substrate comprises glass or plastic (page 7, lines 3-12).

Regarding Claim 34, Walt et al disclose the microarray wherein the substrate is flexible i.e. optical fiber (page 7, lines 18-20). It is noted that Claim 34 depends from Claim 25. For purposes of examination, the claim is interpreted as depending from Claim 27.

11. Claims 1-8, 12-13, 24 and 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (U.S. Patent Application Publication No. 2002/0015952, filed 1 February 2001) in view of McGall et al (U.S. Patent No. 6,147,205, filed 5 March 1997).

Regarding Claim 1, Anderson et al disclose a coating composition comprising a gelling agent and microspheres dispersed in a fluid i.e. the gelling agent fluid (¶ 81 and 86) wherein upon coating the composition on a substrate, said microspheres become immobilized in the plane of coating and form a random pattern on the substrate (¶ 131-133) i.e. the gel comprising microspheres are introduced in to tubes which are then sliced and placed on a substrate to coat the substrate microspheres immobilized in a non-specific pattern i.e.

randomly (Fig. 2-3) wherein the gelling agent is polyacrylamide (¶ 86) which is defined as a gelling agent by the specification (page 5, lines 1-15)

Anderson et al do not teach the composition comprises a coating aid. However, coating aids were well known in the art a the time the claimed invention was made as taught by McGall et al. Mc Gall et al specifically teach a coating composition for making a microarray wherein the composition comprises a gelling agent e.g. polyethylene glycol and a coating aid e.g. Triton X-100 (Column 14, lines 4-35). Furthermore McGall et al teach that adding the coating aid to the composition promotes spreading and adhesion of the gelling agent, limits evaporation and promotes longevity of the coated surface (Column 14, lines 29-35). Therefore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the coating composition of Anderson et al by adding the coating aid as taught by McGall et al for the expected benefit of promoting spreading and adhesion of the gelling agent, limiting evaporation and promoting longevity of the coated surface as taught by Walt et al (Column 14, lines 29-35).

Regarding Claim 2, Anderson et al disclose the composition wherein the substrate is characterized by an absence of specific sites capable of interacting with the microspheres i.e. the substrate is solid surface e.g. glass slide and therefore is characterized by the absence of specific sites e.g. wells capable of physically interacting with the microspheres (¶ 133).

Regarding Claim 3, Anderson et al disclose the composition wherein the random pattern is preserved (i.e. the orientation is maintained) upon gelling of the gelling agent (¶ 131).

Regarding Claim 4, Anderson et al disclose the composition wherein the microspheres can bear surface active sites (¶ 81).

Regarding Claim 5, Anderson et al disclose the composition wherein the surface active sites can carry organic or inorganic attachments (¶ 81).

Regarding Claim 6, Anderson et al disclose the composition wherein the surface of the active site is capable of chemical or physical interaction (¶ 81).

Regarding Claim 7, Anderson et al disclose the composition wherein the surface active site is bioactive (¶ 81).

Regarding Claim 8, Anderson et al disclose the composition wherein the bioactive site interacts with nucleic acid, protein or fragment thereof (¶ 81).

Regarding Claim 12, Anderson et al disclose the composition wherein the gelling agent is gelatin (¶ 86).

Regarding Claim 13, Anderson et al disclose the composition wherein the gelling agent undergoes thermal gelation (Table 1 and ¶ 112).

Regarding Claim 24, Anderson et al disclose the composition wherein the microsphere contains a surface active site comprising a functionality selected from the group consisting of carboxy, amine, epoxy, hydrazine, aldehyde and combinations thereof (¶ 81).

Regarding Claim 27, Anderson et al disclose a microarray comprising a substrate coated with a composition comprising microspheres dispersed in a fluid wherein the microspheres are immobilized at random positions on the substrate (¶ 81 and 131-133) wherein the gelling agent is polyacrylamide (¶ 86) which is defined as a gelling agent by the specification (page 5, lines 1-15)

Anderson et al do not teach the composition comprises a coating aid. However, coating aids were well known in the art a the time the claimed invention was made as taught by McGall et al. Mc Gall et al specifically teach a coating composition for making a microarray wherein the composition comprises a gelling agent e.g. polyethylene glycol and a coating aid e.g. Triton X-100 (Column 14, lines 4-35). Furthermore McGall et al teach that adding the coating aid to the composition promotes spreading and adhesion of the gelling agent, limits evaporation and promotes longevity of the coated surface (Column 14, lines 29-35). Therefore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the coating composition of Anderson et al by adding the coating aid as taught by McGall et al for the expected benefit of promoting spreading and

adhesion of the gelling agent, limiting evaporation and promoting longevity of the coated surface as taught by Walt et al (Column 14, lines 29-35).

Regarding Claim 28, Anderson et al disclose the microarray wherein the substrate is free of receptors designed to physically interaction with the microspheres i.e. the substrate is solid surface e.g. glass slide and therefore is characterized by the absence of specific sites e.g. wells capable of physically interacting with the microspheres (¶ 133).

Regarding Claim 29, Anderson et al disclose the composition wherein the random pattern is preserved (i.e. the orientation is maintained) upon gelling of the gelling agent (¶ 131).

Regarding Claim 30, Anderson et al disclose the microarray wherein the gelling agent is gelatin (¶ 86).

Regarding Claim 31, Anderson et al disclose the microarray wherein the microspheres bear chemically active sites (¶ 81).

Regarding Claim 32, Anderson et al disclose the microarray wherein the chemically active site is bioactive (¶ 81).

Regarding Claim 33, Anderson et al disclose the microarray wherein the substrate comprises glass or plastic (¶ 81).

Regarding Claim 34, Anderson et al disclose the microarray wherein the substrate is flexible i.e. flexible film (¶ 133).

12. Claims 12-14 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (WO 00/16101, published 23 March 2000) in view of McGall et al (U.S. Patent No.

6,147,205, filed 5 March 1997) as applied to Claims 1 and 27 above and further in view of Anderson et al (U.S. Patent Application Publication No. 2002/0015952, filed 1 February 2001).

Regarding Claim 12, Walt et al teach a coating composition comprising a gelling agent and microspheres dispersed in a fluid (page 22, lines 9-22) wherein upon coating the composition on a substrate, said microspheres become immobilized in the plane of coating and form a random pattern on the substrate i.e. the microspheres are held in place by the gelling agent (page 22, lines 15-16) wherein the gelling agent is a known gelling agent permeable to aqueous species (page 22, lines 19-22) but they do not specifically teach the gelling agent is gelatin. However, Anderson et al teach the similar composition comprising a gelling agent and microspheres dispersed in a fluid i.e. the gelling agent fluid (¶ 81 and 86) wherein upon coating the composition on a substrate, said microspheres become immobilized in the plane of coating and form a random pattern on the substrate (¶ 131-133) wherein the gelling agent is gelatin which, unlike other gelling agents, sets at a temperature below ambient temperature (¶ 86, lines 18-21). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the gelatin gelling agent of Anderson et al to the gelling agent of Walt et al to thereby use a gelling agent which gels at ambient temperature for the obvious benefits of convenience and simplicity of gelling.

Regarding Claim 13, Walt et al teach the composition wherein the gelling agent is a known gelling agent permeable to aqueous species (page 22, lines 19-22) but they do not specifically teach a gelling agent which requires thermal gelation. Anderson et al teach the similar composition wherein the gelling agent requires thermal gelation whereby the physical dimensions of the gelled composition is altered by applying heat i.e. a macro array is "shrunk" to a microarray (¶ 112). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the thermal gelation of Anderson et al to the gelling agent of Walt et al whereby a macroarray becomes a microarray by simple application of heat. One of ordinary skill in the art would have been motivated apply the thermal gelation

of Anderson et al to create a microarray because this method would simplify microarray production by eliminating the need for micro-scaled tools. Therefore, it would have been obvious to one of ordinary skill in the art to apply the thermal gelation of Anderson et al to the gelling of Walt et al for the expected benefit of simplifying microarray production.

Regarding Claim 14, Walt et al teach the composition is used for a wide variety of chemical and physical interactions (pages 35-36) but they are silent regarding alkali pretreatment of the gel. Anderson et al teach their similar composition is also used for a wide variety of chemical and physical interactions and wherein the environmental conditions for reactions within the composition vary for different reactions (¶ 54). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the gelling agent of Walt et al by alkali pretreating the gelling agent as claimed based on the interaction to be detected for the obvious benefit of facilitating binding of the agents of interest as taught by Anderson et al (¶ 54).

Regarding Claim 30, Walt et al teach a microarray comprising a substrate coated with a composition comprising microspheres dispersed in a fluid wherein the microspheres are immobilized at random positions on the substrate (page 22, lines 9-22) wherein the gelling agent is a known gelling agent permeable to aqueous species (page 22, lines 19-22) but they do not specifically teach the gelling agent is gelatin. However, Anderson et al teach the similar composition comprising a gelling agent and microspheres dispersed in a fluid i.e. the gelling agent fluid (¶ 81 and 86) wherein upon coating the composition on a substrate, said microspheres become immobilized in the plane of coating and form a random pattern on the substrate (¶ 131-133) wherein the gelling agent is gelatin which, unlike other gelling agents, sets at a temperature below ambient temperature (¶ 86, lines 18-21). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the gelatin gelling agent of Anderson et al to the gelling agent of Walt et al to thereby use a

gelling agent which gels at ambient temperature for the obvious benefits of convenience and simplicity of gelling.

13. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (WO 00/16101, published 23 March 2000) in view of McGall et al (U.S. Patent No. 6,147,205, filed 5 March 1997) as applied to Claims 1 and 27 above and further in view of Chang et al (U.S. Patent No. 4,873,102, issued 10 October 1989).

Regarding Claim 26, Walt et al teach a coating composition comprising a gelling agent and microspheres dispersed in a fluid (page 22, lines 9-22) wherein upon coating the composition on a substrate, said microspheres become immobilized in the plane of coating and form a random pattern on the substrate i.e. the microspheres are held in place by the gelling agent (page 22, lines 15-16) wherein the microspheres contain a polymeric material comprising methylstyrene and divinylbenzene (page 17, lines 21-23) but they are silent regarding the polymerization method. However, emulsion polymerization preparation of microspheres was well known in the art at the time the claimed invention was made as taught by Change et al (Example 1, Column 6, lines 25-57) wherein the method provides microspheres of very narrow size range. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the emulsion polymerization of Change et al to the microspheres of Walt et al to thereby provide microspheres of a uniform size as taught by Chang et al (Column 6, lines 26-28) for the obvious benefits of providing consistent microsphere surface area for surface interaction and thereby controlling interaction uniformity.

**Response to Arguments**

14. Regarding Walt et al, Applicant argues Walt does not use a coating aid or that the solution gels but instead relies upon evaporation of a film. The argument has been considered but as stated above, the specification defines the instantly claimed gelling agent. Walt et al teach gelling agent is selected from polyethylene glycol and polyacrylamide (page 22, lines 20-22) as defined by the specification.

Applicant argues that neither Walt or McGall teach a solution containing microspheres that form a gel. The argument has been considered but is not found persuasive for the reasons stated immediately above. Furthermore, the instant claims are drawn to a composition comprising elements "capable of" forming a gel. The instant specification defines such elements and Walt teaches those element. The intended use of the composition i.e. forming a gel does not limit the elements of the claims.

Regarding Anderson et al, Applicant argues that the reference does not teach immobilizing the microspheres on the surface of the substrate wherein the gelling agents are those defined in the specification. In response to applicant's argument that the references fail to show certain features of applicant's invention, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding the combination of Walt et al and Anderson et al, Applicant argues that the references do not provide a motivation for combining the teachings. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Anderson et al provide the motivation to replace the gelling agent of Walt et al with a gelatin gelling agent i.e. the gelling agent is gelatin which, unlike other gelling agents, sets at a temperature below ambient temperature (¶ 86, lines 18-21) and therefore does not require further treatment and/or heat for gelling. Anderson further provide motivation for using gelling agent which undergoes thermal gelation i.e. a microarray is produced by simply shrinking a macro array (¶ 112).

**Conclusion**

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741 until 13 January 2004. The examiner can normally be reached on 6:00 TO 3:30 Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-0507.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
February 4, 2004